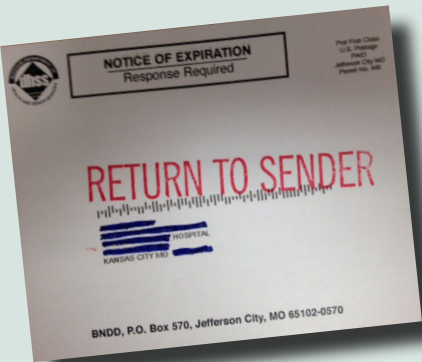


Rx News Bulletin

Bureau of Narcotics & Dangerous Drugs

Missouri Department of Health and Senior Services

health.mo.gov/safety/bndd/index.php

Registrants in Hospitals Not Receiving Mail

When registrants submit applications for registrations, they are asked to provide their primary practice location. During this process, they are also given an option of providing a separate mailing address. The Bureau of Narcotics and Dangerous Drugs will always send mail to the mailing address requested. If no separate mailing address is provided, then the address used defaults to the practice address.

Registrants in hospitals have difficulty in receiving mail if they do not include information in their addresses such as mail stop numbers, campus boxes or the name of their department. The Bureau sends mail to registrants in Missouri hospitals and the mail is sometimes returned by the hospital mail room because there was no department name or mail stop number.

All registrants who would like to receive their mail at a hospital are asked to verify that they have provided the BNDD with their full address in order to get mail delivered in the hospital.

Prescribers Are Not Authorized to Use Sticker Labels on Prescriptions

The Bureau has received multiple inquiries regarding controlled substance prescriptions where the prescriber has placed labels on the prescription that bears the patient's name and address, or sometimes the drug information. The Bureau was asked if the use of labels is permitted.

Federal Regulation 21 CFR 1306.05(d) is titled, "Manner of Issuance of Prescriptions." Paragraph (d) of the federal regulation states that a prescription may be handwritten in ink or indelible pencil. It may be typed on a typewriter or printed on a computer printer.

The federal regulation does not authorize prescribers to place a label on the face of the prescription. There have been issues in the past where patients peeled labels off of the prescription forms and used them to divert drugs on other blank forms. There have also been issues where after a period of time the glue dries out and the label falls off the prescription form. As a result, the pharmacy is left with a blank prescription form with no label attached to it.

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DEA Moves Hydrocodone Products into Schedule II

Until recently, combination drug products containing hydrocodone were placed into Schedule III by the United States Drug Enforcement Administration (DEA). This will change during the first week of October 2014. The DEA has previously published their intent to re-schedule hydrocodone products into Schedule II. The DEA published their final rule in August 2014. After a 45-day period the federal regulation will become official and all hydrocodone products will become Schedule II during the first week of October 2014.

The will impact Missouri registrants in the following ways:

- In a pharmacy, all hydrocodone products will have to be locked in a safe or cabinet similar to all other Schedule II drugs. These products may no longer be dispersed on the shelves.
- All of the prescribing laws for Schedule II drugs will apply. Originally signed prescriptions are required. Emergency prescriptions may only be telephoned by a physician. Faxes may only be used for patients in hospice or long-term care facilities.
- DEA Official Order Forms will have to be used to transfer possession.
- Mid-level practitioners in Missouri will not have authority with hydrocodone products.
- No Schedule II prescriptions may have refills on them pursuant to statute.
- A routine prescription is for 30 days or less.

Any prescription for more than a 30-day supply has to document the medical reason for the extended supply. This must be a medical reason that describes the diagnosis and current status or condition and reason for the supply. A diagnosis code number is not sufficient. It must be a medical reason and cannot be because a patient is going to be gone traveling or there is better price break on a bigger supply.

DEA Places Tramadol in Schedule IV

In August the United States Drug Enforcement Administration (DEA) placed tramadol into Schedule IV. Both the DEA and the published pharmacy reference manual, Facts and Comparisons, have list tramadol as an opiate analgesic. Missouri registrants are reminded of the following issues regarding this new scheduling:

- Individual practitioners must have tramadol locked in a safe or cabinet.
- Pharmacies may continue to disperse tramadol amongst other drug stock similar to other Schedule IV medications.
- Registrants should immediately perform an inventory count of tramadol and staple it to their annual inventory document.
- All controlled substance recordkeeping laws apply for maintaining receipt records, inventories, dispensing records, transfers, administration and wastage.
- The maximum that may be prescribed or dispensed at one time is a 90-day supply.
- Prescriptions are valid if they were issued by a practitioner with a DEA number. Any tramadol prescriptions issued by a person without a DEA number is no longer valid.
- Tramadol is listed in Schedule IV so there are no restrictions placed on advanced practice nurses or physicians' assistants. The restrictions for mid-level practitioners in Missouri statute are only for Schedules II and III.

DEA Announces New Rules for Drug Disposal

The DEA recently published new rules for the disposal of unwanted controlled substances. The state is currently reviewing these new federal rules. The Missouri Bureau of Narcotics and Dangerous Drugs is reviewing these rules to see what changes will be required in Missouri. Any new rules or amendments will be published and filed at the Secretary of State's Office in the Missouri Register.



Veterinary Medicine Mobility Act of 2014

NO Major Impact to Missouri Veterinarians

Both the federal and state controlled substance statutes mandate that a separate controlled substance registration is required for each separate place where controlled substances are administered or dispensed. Agencies also have the authority to promulgate rules for the efficient and effective enforcement of laws. The Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) and the local United States Drug Enforcement Administration (DEA) offices in Missouri have accepted that practitioners sometimes make house calls. Registrants are required to be registered at their principle place of business. They are required to have registrations and maintain records at locations where they stock and dispense drugs. The BNDD authorizes practitioners to make house calls to patients' homes as long as drug security and required records are maintained. However, practitioners may not take controlled drugs to other office or practice locations to conduct business at these sites.

In other parts of the country there were interpretations on whether or not veterinarians could make house calls and take drugs into the field, without additional registrations. In order to clarify this authority, President Obama recently signed the Veterinary Medicine Mobility Act. This law amends the Controlled Substances Act of 1970 by clarifying that veterinarians may transport and dispense controlled substances at other locations, under their one existing DEA registration, in their usual course

of veterinary practice, as long as the veterinarian is licensed in the state where care occurs, and as long as the additional site is not a principal place of business or professional practice. In other words, veterinarians can take drugs into the field to make house calls but they cannot take drugs to another place of business or professional practice.

This new federal law does not have an impact on Missouri's existing laws for controlled substances. Missouri's laws remain the same as follows:

- All persons must have a Missouri Controlled Substances Registration from the BNDD before conducting any activities with controlled substances in Missouri;
- The practitioners must provide a Missouri practice address where controlled drug operations are based, where patient care occurs and records are kept. Practitioners must have a Missouri location where state authorities can conduct inspections and investigations;
- If an out-of-state veterinarian wants to come into Missouri and make a house call, that veterinarian must have a professional license and a BNDD registration at a Missouri practice address that is maintained. Out-of-state veterinarians must establish a Missouri location.

States have the authority to have stricter laws and

requirements than the federal government. The current laws in Missouri are consistent over the past 44 years in that:

1. Although physicians in a hospital may not have their own DEA number and they may use the hospital's DEA number, but each physician in Missouri is required to have their own personal state BNDD registration.
2. Although veterinarians are not required to have their own DEA number and they may perform limited tasks under the authority of their practice owner's DEA number, each veterinarian in Missouri is required to have their own individual state BNDD registration.

State agencies have primary inspection and enforcement authority over practitioners. It is the state agencies that primarily respond to citizens' complaints. The current laws enacted over 44 years ago have provided consistency and clarity in jurisdiction. The current laws that exist in Missouri will continue to prevent the following problems:

- Practitioners coming from out of state enter Missouri, provide care and leave. When complaints are filed it is much more difficult to follow up on an out-of-state doctor that is not properly registered and does not have records that can be inspected in Missouri.
- Missouri investigators do not have authority to leave Missouri and investigate the doctors who have returned to their home state.
- When Missouri citizens and investigators file a complaint with a medical board in another state, that other state may say that they have no authority because the incident and care took place in Missouri.
- Practitioners can enter Missouri and provide care and earn income. Without a Missouri registration, the practitioners could provide care and earn income that is not reported for tax purposes. This would place Missouri practitioners at a disadvantage.

Under this new federal law enacted in August 2014, an out-of-state veterinarian can obtain a Missouri professional license. They must first obtain a state controlled drug registration at a Missouri practice location where drug activities take place, where patient care occurs and where records are kept. They would still be required to obtain a federal DEA registration because this would be a location of a principal place of business and professional practice. Our existing Missouri veterinarians can continue to make house calls in Missouri as they always have.



BNDD Attends Missouri Emergency Medical Services Association Conference

The Bureau of Narcotics and Dangerous Drugs (BNDD) attended the annual Missouri Emergency Medical Services Association (MEMSA) conference in Branson, Missouri. The Bureau conducted a class on complying with controlled substance record keeping and security laws. As a result of the conference interaction, the Bureau worked with the Bureau of Emergency Medical Services (BEMS) to send out a state-wide email to address the requirements for registrants to perform background checks on employees before granting them access to controlled substances.



The Bureau of Narcotics and Dangerous Drugs conducts an educational presentation at the Missouri Emergency Medical Services Association

The BNDD conducts educational presentations throughout the year for various organizations and entities. Topics include prescription drug abuse, investigating prescription fraud, destruction of unwanted medications, complying with state and federal drug laws, record keeping, and security. If you are interested in having a BNDD representative conduct a presentation for your organization, please contact us at 573-751-6321. BNDD will be presenting at these upcoming conferences:

- September 30, 2014 – Missouri Blueprint for Safety – Prescription Drug Abuse in Missouri
- October 27, 2014 – Missouri Deputy Sheriff's Association – Investigating Prescription Fraud
- January 23, 2015 – Missouri Veterinary Medical Association Convention

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